

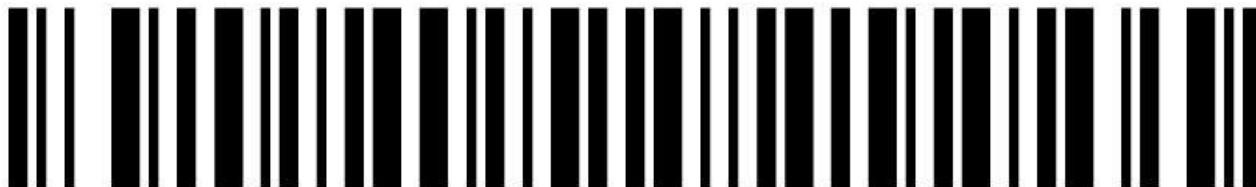
DELFLEX NEUTRAL PH WITH ATTACHED STAY-SAFE EXCHANGE SET - dextrose monohydrate, sodium chloride, calcium chloride, magnesium chloride and sodium lactate injection

Fresenius Medical Care North America

Peritoneal Dialysis Solutions

With Attached stay•safe® Exchange Set

For Intraperitoneal Administration Only



89-905-65 Rev. 09/09

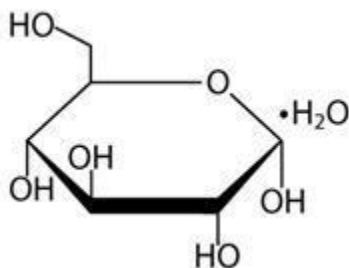
NO LATEX

DESCRIPTION

DELFLEX® Neutral pH peritoneal dialysis solutions (supplied in standard, low magnesium and low magnesium/low calcium as 2 or 3 Liter product) are sterile, non-pyrogenic formulations of dextrose and electrolytes in water for injection, USP, for use in peritoneal dialysis. In comparison to conventional peritoneal dialysis solutions, DELFLEX® Neutral pH solutions are formulated to lower levels of glucose degradation products and provide a neutral pH of 7.0 ± 0.4 , which is closer to the physiologic pH. The osmotic and buffer solutions are stored separately and mixed by the patient prior to use. The stay•safe® exchange set utilizes an easy to use dial designed to eliminate the use of clamps and to prevent touch contamination of internal connection components. Composition, calculated osmolarity, pH and ionic concentrations of the mixed solutions are shown in Table 2.

Hydrochloric acid and sodium hydroxide may be added for pH adjustment. The patient mixed solution pH is 7.0 ± 0.4 .

Dextrose USP is chemically designated D-glucose monohydrate ($C_6H_{12}O_6 \cdot H_2O$) a hexose sugar freely soluble in water. The structural formula is shown here:



These solutions do not contain antimicrobial agents or additional buffers. Exposure to temperatures above $25^{\circ}C/77^{\circ}F$ during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. Since the flexible inner bag is compounded from a specific polyvinyl chloride, water may permeate from the inner bag into the outerwrap in quantities insufficient to affect the solution significantly. Solutions in contact with the plastic inner bag can cause certain chemical components of the bag to leach out in very small amounts; however, the safety of the plastic formulation is supported by biological tests for plastic containers.

Nominal glucose degradation product (GDP) levels (immediately following sterilization) in DELFLEX® Neutral pH solution and DELFLEX® solution are reported in Table 1. The clinical relevance of these differences in GDP levels is unknown.

Table 1. Glucose Degradation Product Levels*

Dextrose Concentration	DELFLEX® Neutral pH	DELFLEX®
1.5%	23	267
2.5%	51	362
4.25%	106	437

*This is the sum ($\mu\text{mol/L}$) of the various component GDPs including: formaldehyde, acetaldehyde, furaldehyde, glyoxal, methylglyoxal, 5-hydroxymethylfurfural (5-HMF), and 3-deoxyglucosone (3DG).

Table 2. Composition, Calculated Osmolarity, pH, and Ionic Concentration

2 Liter DELFLEX[®] Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
		Main Bag Contents								
Composition 100ml	Dextrose Hydrous, USP (C ₆ H ₁₂ O ₆ • H ₂ O)	1.52g	2.56g	4.36g	1.54g	2.56g	4.36g	1.54g	2.56g	4.36g
	Sodium Chloride, USP (NaCl)	581mg	581 mg	581mg	552mg	552 mg	552 mg	552 mg	552 mg	552 mg
	Calcium Chloride, USP (CaCl ₂ • 2H ₂ O)	26.3mg	26.3mg	26.3mg	26.3mg	26.3mg	26.3mg	18.9mg	18.9mg	18.9mg
	Magnesium Chloride, USP (MgCl ₂ • 6H ₂ O)	15.6mg	15.6mg	15.6mg	5.21mg	5.21mg	5.21mg	5.21mg	5.21mg	5.21mg
		Mini-bag Contents								
	Sodium Lactate(C ₃ H ₅ NaO ₃)	15.4mg	14.4mg	14.4mg	16.7mg	16.7mg	16.7mg	16.7mg	16.7mg	16.7mg
	Sodium Bicarbonate(NaHCO ₃)	1.20g	1.20g	1.20g	1.20g	1.20g	1.20g	1.20g	1.20g	1.20g
		Total ingredient content AFTER mixing Main Bag and Mini-bag solutions								
	Dextrose Hydrous, USP (C ₆ H ₁₂ O ₆ • H ₂ O)	1.5g	2.5g	4.25g	1.5g	2.5g	4.25g	1.5g	2.5g	4.25g

Sodium Chloride, USP (NaCl)	567mg	567mg	567mg	538mg	538mg	538mg	538mg	538mg	538mg
Sodium Lactate(C3H5NaO3)	553mg	353mg	353mg	409mg	409mg	409mg	409mg	409mg	409mg
Sodium Bicarbonate(NaHCO3)	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg
Calcium Chloride, USP (CaCl2• 2H2O)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
Magnesium Chloride, USP (MgCl2 • 6H2O)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
Osmolarity(mOsmoL/L)(calc)	347	398	486	346	396	485	344	394	483
pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0

Main Bag Contents

Ionic Composition (mEq/L)	Sodium	99.4	99.4	99.4	94.3	94.3	94.3	94.3	94.3	94.3
	Calcium	3.59	3.59	3.59	3.59	3.59	3.59	2.56	2.56	2.56
	Magnesium	1.54	1.54	1.54	0.51	0.51	0.51	0.51	0.51	0.51
	Chloride	105	105	105	98.4	98.4	98.4	97.4	97.4	97.4
	Mini-bag Contents									
	Sodium	1428	1428	1428	1632	1632	1632	1632	1632	1632
	Lactate	1285	1285	1285	1489	1489	1489	1489	1489	1489
	Bicarbonate	143	143	143	143	143	143	143	143	143
	Total ingredient content AFTER mixing Main Bag and Mini-bag solutions									
	Sodium	132	132	132	132	132	132	132	132	132
	Calcium	3.5	3.5	3.5	3.5	3.5	3.5	2.5	2.5	2.5
	Magnesium	1.5	1.5	1.5	0.5	0.5	0.5	0.5	0.5	0.5
	Chloride	102	102	102	96	96	96	95	95	95
	Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5

Bicarbonate	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5
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3 Liter DELFLEX® Neutral pH

		Standard Magnesium, Standard Calcium			Low Magnesium, Standard Calcium			Low Magnesium, Low Calcium		
		1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose	1.5% Dextrose	2.5% Dextrose	4.25% Dextrose
		Main Bag Contents								
Composition 100ml	Dextrose Hydrous, USP (C ₆ H ₁₂ O ₆ • H ₂ O)	1.52 g	2.54 g	4.32g	1.52g	2.54 g	4.32g	1.52g	2.54g	4.32g
	Sodium Chloride, USP (NaCl)	576mg	576 mg	576 mg	547mg	547 mg	547 mg	547 mg	547 mg	547mg
	Calcium Chloride, USP (CaCl ₂ • 2H ₂ O)	26.1mg	26.1mg	26.1mg	26.1mg	26.1mg	26.1mg	18.7mg	18.7mg	18.7mg
	Magnesium Chloride, USP (MgCl ₂ • 6H ₂ O)	15.4mg	15.4mg	15.4mg	5.16mg	5.16mg	5.16mg	5.16mg	5.16mg	5.16mg
	Mini-bag Contents									
	Sodium Lactate(C ₃ H ₅ NaO ₃)	21.6mg	21.6mg	21.6mg	25.0mg	25.0mg	25.0 mg	25.0mg	25.0 mg	25.0 mg
	Sodium Bicarbonate(NaHCO ₃)	1.80g	1.80 g	1.80g	1.80g	1.80g	1.80g	1.80g	1.80g	1.80g
	Total ingredient content AFTER mixing Main Bag and Mini-bag solutions									
	Dextrose Hydrous, USP	1.5g	2.5g	4.25g	1.5g	2.5g	4.25g	1.5g	2.5g	4.25g

(C ₆ H ₁₂ O ₆ • H ₂ O)									
Sodium Chloride, USP (NaCl)	567mg	567mg	567mg	538mg	538mg	538mg	538mg	538mg	538mg
Sodium Lactate (C ₃ H ₅ NaO ₃)	353mg	353mg	353mg	409mg	409mg	409mg	409mg	409mg	409mg
Sodium Bicarbonate (NaHCO ₃)	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg	29.4mg
Calcium Chloride, USP (CaCl ₂ • 2H ₂ O)	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	25.7 mg	18.4 mg	18.4 mg	18.4 mg
Magnesium Chloride, USP (MgCl ₂ • 6H ₂ O)	15.2 mg	15.2 mg	15.2 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg	5.08 mg
Osmolarity(mOsmoL/L)(calc)	347	398	486	346	396	485	344	394	483
pH 7.0 ± 0.4	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0	7.0

Main Bag Contents

Ionic Composition (mEq/L)	Sodium	98.6	98.6	98.6	93.5	93.5	93.5	93.5	93.5
	Calcium	3.56	3.56	3.56	3.56	3.56	2.54	2.54	2.54
	Magnesium	1.52	1.52	1.52	0.51	0.51	0.51	0.51	0.51
	Chloride	104	104	104	97.6	97.6	97.6	96.6	96.6
	Mini-bag Contents								
	Sodium	2142	2142	2142	2448	2448	2448	2448	2448
	Lactate	1927	1927	1927	2233	2233	2233	2233	2233
	Bicarbonate	214	214	214	214	214	214	214	214
	Total ingredient content AFTER mixing Main Bag and Mini-bag solutions								
	Sodium	132	132	132	132	132	132	132	132
	Calcium	3.5	3.5	3.5	3.5	3.5	2.5	2.5	2.5
	Magnesium	1.5	1.5	1.5	0.5	0.5	0.5	0.5	0.5
	Chloride	102	102	102	96	96	96	95	95

Lactate	31.5	31.5	31.5	36.5	36.5	36.5	36.5	36.5	36.5
Bicarbonate	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5

CLINICAL PHARMACOLOGY

Peritoneal dialysis is the process of filtering excess water and toxins from the bloodstream through a semi-permeable membrane. This process does not cure the disease, but prevents progression of symptoms. Dialysis for chronic kidney failure is essential to maintain life, unless the patient receives a kidney transplant. A peritoneal dialysis procedure utilizes the peritoneum (lining of the abdomen) as the semi-permeable membrane. The procedure is conducted by instilling peritoneal dialysis solution through a catheter in the abdomen into the peritoneal cavity. Since the peritoneum is heavily supplied with blood vessels, the contact of the solution with the peritoneum causes excess water and toxins in the bloodstream to be drawn across the membrane into the solution. This osmosis and diffusion occurs between the plasma of the patient and the peritoneal dialysis solution. After a period of time called “dwell time,” the solution is then drained from the patient.

This solution does not contain potassium. In situations in which there is a normal serum potassium level or hypokalemia, the addition of potassium chloride (up to a concentration of 4 mEq/L) may be indicated to prevent severe hypokalemia.

Addition of potassium chloride should be made after careful evaluation of serum and total body potassium and only under the direction of a physician.

Clinical studies have demonstrated that the use of low magnesium solutions resulted in significant increases in serum CO₂ and decreases in serum magnesium levels. The decrease in magnesium levels did not cause clinically significant hypomagnesemia.

INDICATIONS AND USAGE

DELFLEX[®] peritoneal dialysis solutions are indicated in the treatment of chronic renal failure patients being maintained on peritoneal dialysis when nondialytic medical therapy is judged to be inadequate.

CONTRAINDICATIONS

None Known

WARNINGS

Not for Intravenous Injection.

Use Aseptic Technique.

It is important to mix the buffer (mini-bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once buffer (mini-bag) and main solutions are mixed, medication may be added prior to administration.

Peritoneal dialysis should be done with great care in patients with a number of conditions, including disruption of the peritoneal membrane or diaphragm by surgery or trauma, extensive adhesions, bowel distention, undiagnosed abdominal disease, abdominal wall infection, hernias or burns, fecal fistula or colostomy, tense ascites, obesity, large polycystic kidneys, recent aortic graft replacement, lactic acidosis and severe pulmonary disease. When assessing peritoneal dialysis as the mode of therapy in such extreme situations, the benefits to the patient must be weighed against the possible complications.

Solutions containing lactate ion should be used with great care in patients with metabolic or respiratory alkalosis. Lactate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

An accurate fluid balance record must be kept and the weight of the patient carefully monitored to avoid over or under hydration with severe consequences, including congestive heart failure, volume depletion and shock.

Excessive use of DELFLEX[®] peritoneal dialysis solution with 4.25% dextrose during a peritoneal dialysis treatment can result in significant removal of water from the patient.

Stable patients undergoing maintenance peritoneal dialysis should have routine periodic evaluation of electrolyte blood chemistries and hematologic factors, as well as other indicators that determine the patient's ongoing status.

After removing the outer wrap, check for minute leaks by squeezing the container firmly. If leaks are found, discard the solution because the sterility may be impaired. (A small amount of moisture may be present inside the overwrap, which is normal condensation from the sterilization process).

Serum calcium levels in patients using low calcium concentrations should be monitored and if found to be low, the peritoneal solution in use should be altered to one with a higher calcium concentration.

PRECAUTIONS

General:

Administer only if the solution is clear, all seals are intact, and there is no evidence of leaking.

It is important to mix the buffer (mini-bag) and main solutions thoroughly. Administer within 24 hours after mixing. Once buffer and main solutions are mixed, medication may be added prior to administration.

Do Not Heat In A Microwave Oven

Care should be taken to see that the catheter is inserted completely, since leakage around the catheter, if not controlled, can create edema from subcutaneous infiltration of the dialysis solution. This will also create an inaccurate fluid balance measurement.

DELFLX[®] Peritoneal Dialysis solutions do not include potassium. Potassium chloride should only be added under the direction of a physician after careful evaluation of both serum and total body potassium.

The overwrap must be removed immediately before use and is provided with a “Tear Open” feature to make removal easy. See instructions in Directions for Use section.

Disconnect from disk only when knob is in position 4 (••••).

Aseptic technique must be used throughout the procedure and at its termination in order to reduce the possibility of infection.

Significant loss of protein, amino acids and water soluble vitamins may occur during peritoneal dialysis. Replacement therapy should be provided as necessary.

Laboratory Tests

Serum electrolytes, magnesium, bicarbonate levels and fluid balance should be periodically monitored.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies with DELFLX[®] peritoneal dialysis solutions have not been performed to evaluate the carcinogenic potential, mutagenic potential or effect on fertility.

Pregnancy: Teratology Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with DELFLX peritoneal dialysis solutions. It is also not known whether DELFLX peritoneal dialysis solutions can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DELFLX peritoneal dialysis solutions should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Caution should be exercised when DELFLX peritoneal dialysis solutions are administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse reactions to peritoneal dialysis include mechanical and solution related problems as well as the results of contamination of equipment or improper technique in catheter placement. Abdominal pain, bleeding, peritonitis, subcutaneous infection around a peritoneal catheter, catheter blockage, difficulty in fluid removal, and ileus are among the complications of the procedure.

Solution related adverse reactions might include peritonitis, catheter site infection, electrolyte and fluid imbalances, hypovolemia, hypervolemia, hypertension, hypotension, disequilibrium syndrome and muscle cramping.

If an adverse reaction does occur, institute appropriate therapeutic procedures according to the patient’s needs and conditions, and save the remainder of the fluid in the bag for evaluation if deemed necessary.

DOSAGE AND ADMINISTRATION

DELFLX peritoneal dialysis solutions are provided for intraperitoneal administration only. The mode of therapy, frequency of treatment, formulation, exchange volume, duration of dwell, and length of dialysis should be selected by the physician responsible for the treatment of the individual patient.

To avoid the risk of severe dehydration or hypovolemia and to minimize the loss of protein, it is advisable to select the peritoneal dialysis solution with lowest level of osmolality consistent with the fluid removal requirements for that exchange.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Additives may be incompatible. Do not store solutions containing additives.

For administration see Directions for Use section.

HOW SUPPLIED

DELFLX peritoneal dialysis solutions are delivered in single-dose flexible bags. All DELFLX peritoneal dialysis solutions have overfills declared on the container label. The flexible containers have the capacity for drainage in excess of their stated fill volume for ultrafiltration from the patient.

DELFLX peritoneal dialysis solutions with an attached stay•safe[®] exchange set are available in containers as shown in the Table 2 in the Description section.

Storage Conditions

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Brief exposure to temperatures up to 40°C/104°F may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F).

Keep DELFLX and all medicines out of the reach of children.

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Fresenius Medical Care

Patent Pending

Revised 09/09

Not for Intravenous Injection. Do not microwave.

Warm solution as directed by your healthcare provider.

Directions for Use

Get Ready

1. Clean work surface. Use aseptic technique.

2. Gather supplies:

- Warmed DELFLEX Neutral pH Peritoneal Dialysis bag with the attached stay•safe Exchange Set.
- Povidone iodine prefilled stay•safe cap, a stand alone item provided separately.
- stay•safe[®] organizer, a stand alone item provided separately (Optional; FMCNA recommends its use)
- Prescribed medicine(s) if ordered by your healthcare provider
- Mask

See **Figure A** for identification of each item described above.

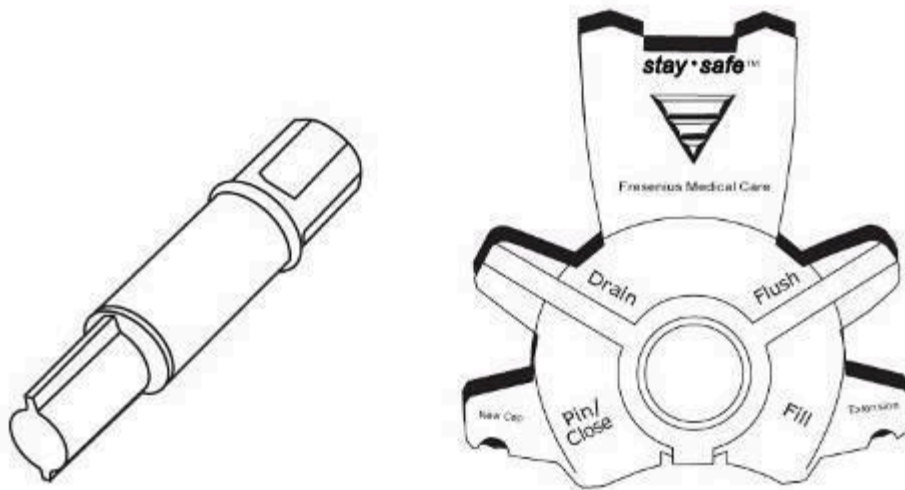
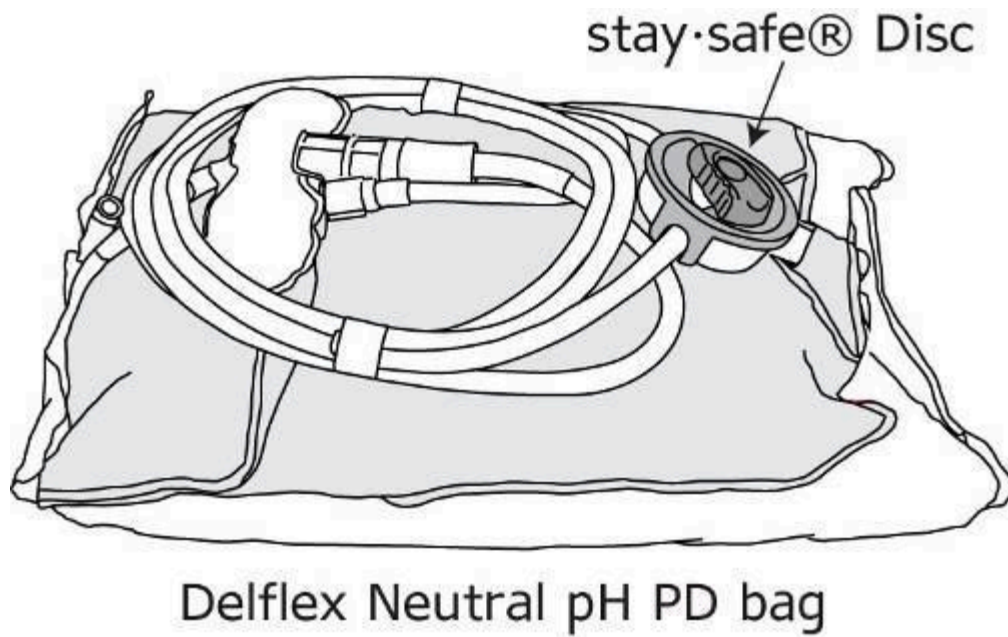


Figure A

3. Put on the mask. Wash your hands.
4. Clamp the Extension Tube Set coming from the catheter.
5. Tear the overwrap across from the slit edge to open. Wipe away any moisture from the solution bags.
6. Inspect DEFLEX Solution Bags:
 - Place the DEFLEX Solution on the work surface. **See Figure B.**

Do Not Microwave

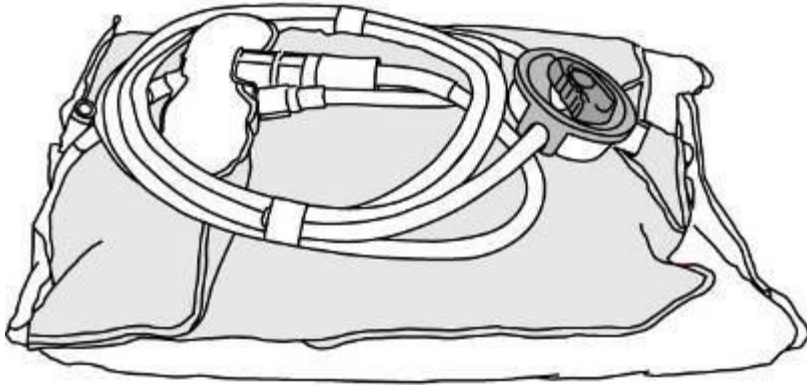


Figure B

- Position solution bags and drain bag as shown in **Figure C**.

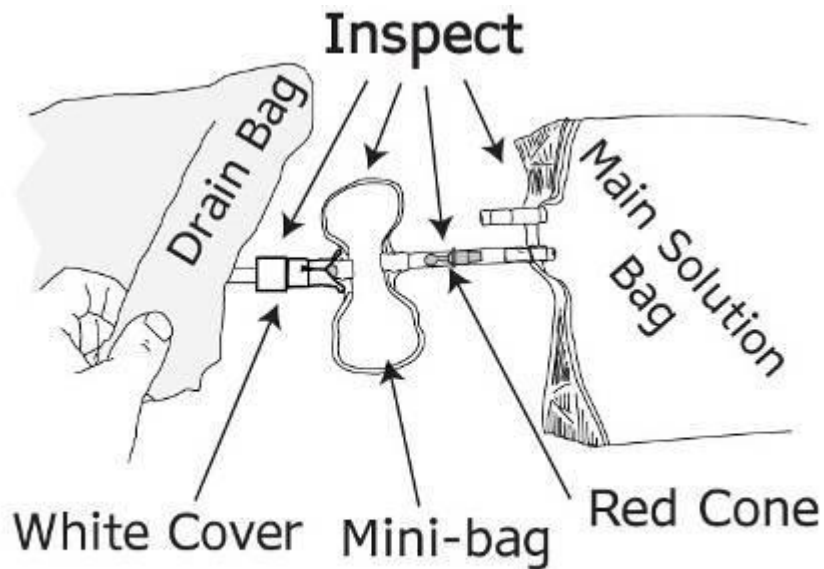


Figure C

- Squeeze the main bag and the mini bag to check for leaks. When squeezing the mini-bag, the bag should remain firm. No solution should leak into the main bag or into the drain line.

Do not use DELFLEX Neutral pH Solution Set if:

- Leaks are found
- The solution bags are damaged
- Solution is cloudy or discolored
- Red or blue cone is broken

Throw away DELFLEX Neutral pH Solution set and notify your healthcare provider.

7. Turn the blue position indicator on the stay•safe® disc counter-clockwise until it fits into the cut-out portion of the colored plastic cover on the disc as illustrated in **Figure D**. This will allow the effluent in your peritoneal cavity to drain. Remove the plastic cover while the indicator is in this position (Position 1: •). Once the cover is removed, do not turn counter-clockwise.

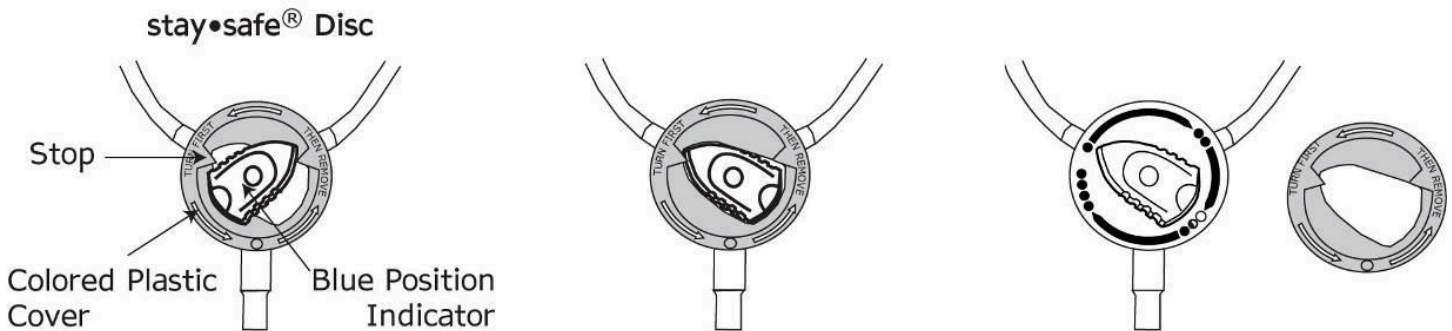


Figure D

Mix Delflex® Neutral pH Solution

Important: Mix the mini-bag and main solutions thoroughly. Use the solution within 24 hours after mixing.

1. With the solution bags stretched out on the work surface, break the red cone by bending. See **Figure E**.

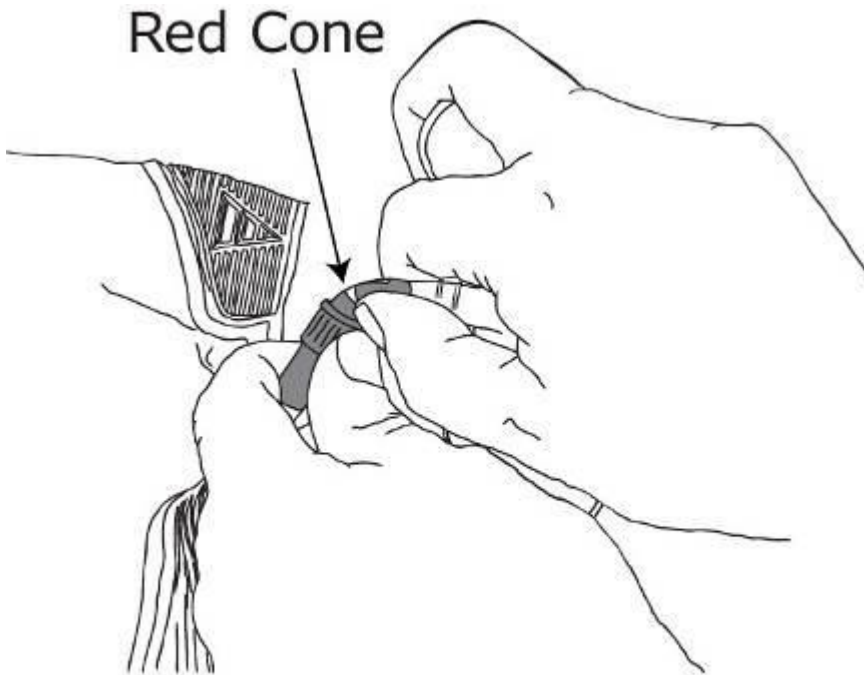
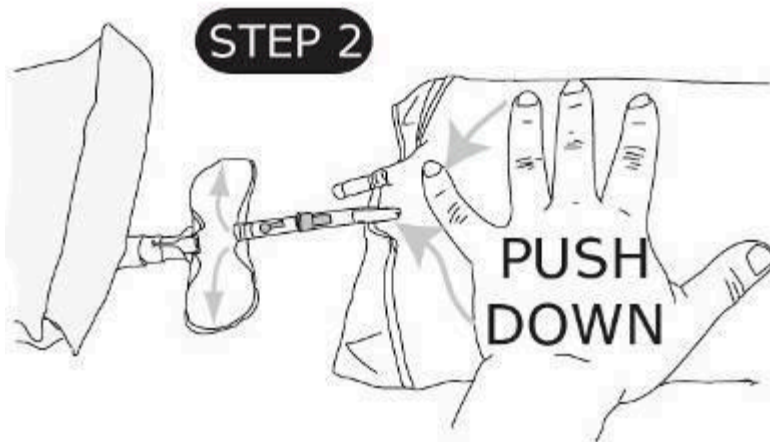
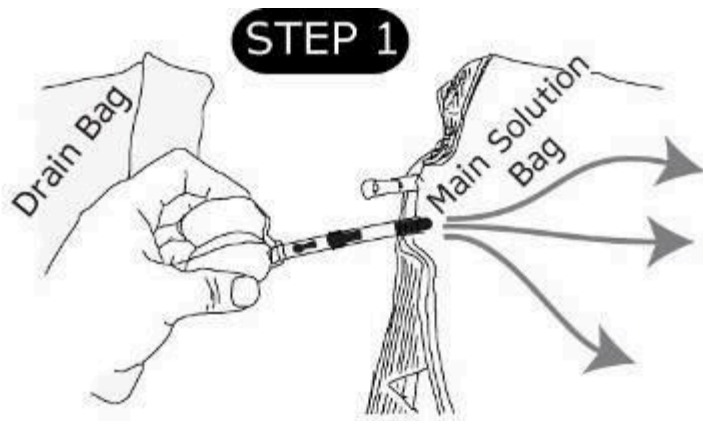


Figure E

2. Fold the min-bag in half. Squeeze the solution from the mini-bag into the main solution bag by pressing the two halves together until the mini-bag is empty. See **Figure F (Step 1)**.



Perform Steps 2 Times

Figure F

3. Push down on main solution bag to flush solution back into the mini-bag. Completely refill mini-bag with solution. See **Figure F (Step 2)**.
4. Repeat steps 2 and 3 above to make sure that all of the contents of the mini-bag have been completely flushed into the main solution bag.
5. Grab the tubing at the bottom of the main solution bag. While keeping the top portion of the bag on the table, flip the bag lengthwise using a back and forth motion to mix solutions. See **Figure G**. Repeat this step to mix solutions.

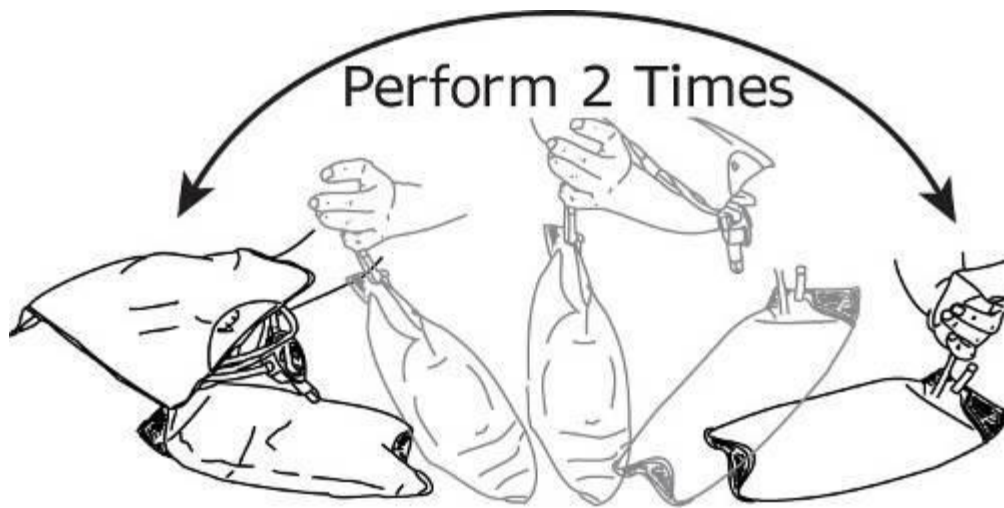


Figure G

6. Fold mini-bag in half and squeeze it until there is no solution left. Slide folded mini-bag into the slit of the white cover to show the blue cone. **See Figure H.**

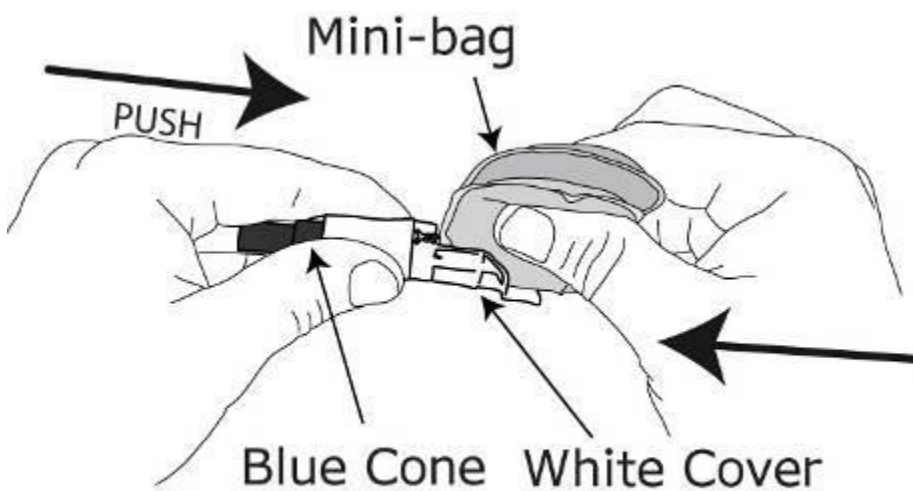


Figure H

The solution is now ready for use.

Administer Peritoneal Dialysis Solution

1. If adding medicine(s):
 - Clean the medication port as instructed by your healthcare provider.
 - Add the medicine(s).
 - Turn the bag upside down several times to mix the medicine.
2. Hang the solution bag from the I.V. pole. Place the drain bag at floor level.
3. Break the blue cone on the bottom of the mini-bag. **See Figure I.** (if using the Organizer, place the stay•safe[®] disc in the organizer as shown in **Figure J**)



Figure I

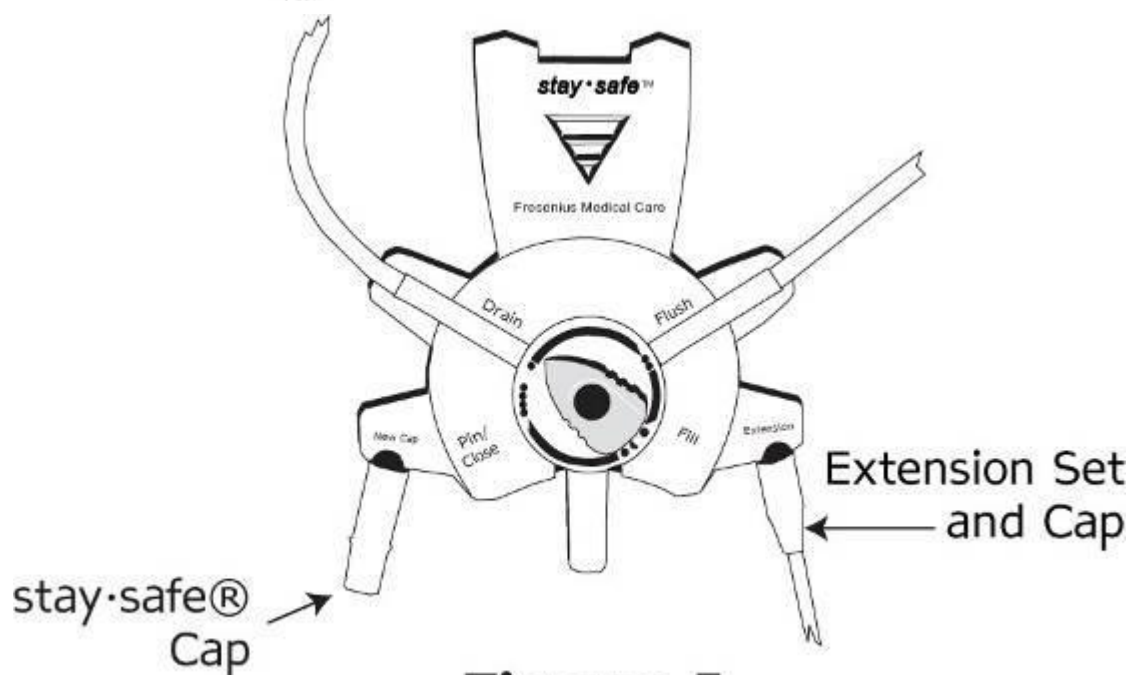


Figure J

4. Remove the new stay•safe® cap from its package. The new stay•safe® cap is the stand alone item provided to the patient separately. Refer to “Get Ready” section for stay•safe® cap identification. (If using the Organizer, place in the right or left notch of the Organizer as illustrated in **Figure J**. Place the existing cap of stay•safe® Extension Set, connected to the patient’s catheter, in the other notch of the Organizer)
5. Remove the cap from the stay•safe disc and throw cap away. Remove the existing cap from the Extension Set connected to the patient’s catheter by twisting the connection counter-clockwise. (If using the Organizer, leave the capped end of the Extension Set in the Organizer and twist the extension set connector counter-clockwise to remove the set from its cap.)
6. Aseptically connect the Extension set to the connector on the stay•safe disc. Twist clockwise to secure the connection.
7. Remove your mask. Do not open the system during exchange.
8. Open the Extension set clamp to start drain.
9. When patient drain is complete, turn the stay•safe® disc position indicator to Position 2 (••). See **Figure K**. This will start flush from the solution bag to the drain bag.

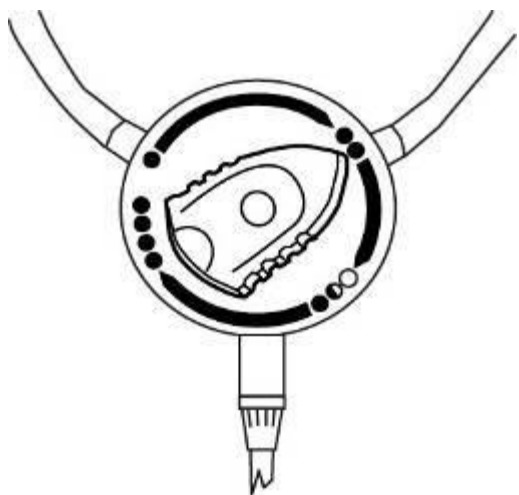


Figure K

10. After approximately 5 seconds turn the stay•safe[®] disc position indicator to Position 3 (●●●). See **Figure L**. This will start the patient fill.

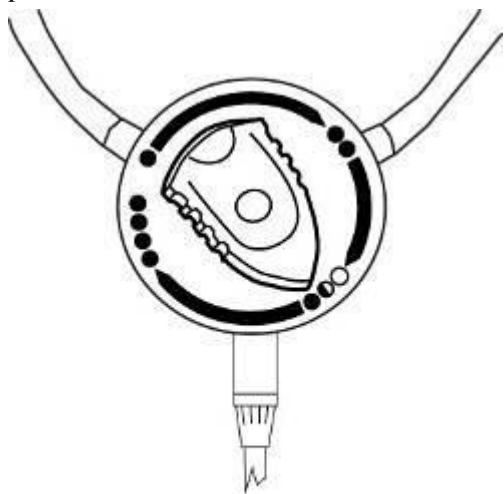


Figure L

11. When fill is complete, turn the stay•safe[®] disc position indicator to Position 4 (●●●●). See **Figure M**. This will insert the closure pin of the disc into the extension set connector and seal the system.

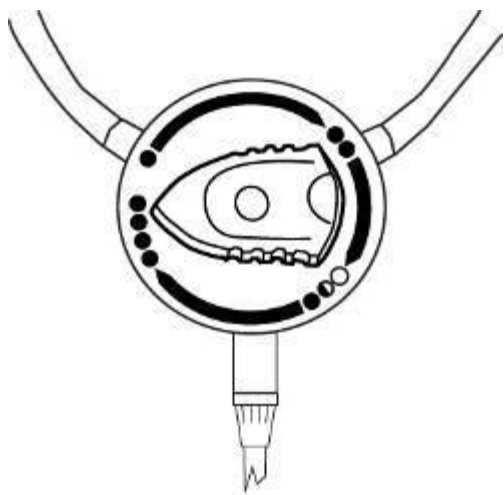


Figure M

12. Remove the white protective cover from the new stay•safe[®] cap. Save for later use.
13. Remove the Extension set from the stay•safe disc and attach the new stay•safe cap. Twist clockwise to secure the connection.
14. Seal the disc by attaching the white protective cover from the stay•safe cap to the disc connector. Twist clockwise to secure the connection and prevent leakage from the used system.
15. Look at the drained fluid for cloudiness. Measure the amount of fluid drained. Throw away the fluid and used set as instructed by your healthcare provider. In case of cloudiness, save the fluid and the exchange set and immediately contact your healthcare provider.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL



(01) 003 49230 188 98 1

DELFLEX® Neutral pH
PERITONEAL DIALYSIS SOLUTION
 with 1.5% DEXTROSE
 and attached **stay•safe®** Exchange Set

CAT. NO. 059-30311

3000 mL

NDC 49230-188-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	1.5 g	-	1.52 g
Sodium Chloride, USP	567 mg	-	576 mg
Sodium Lactate	353 mg	2160 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	15.2 mg	-	15.4 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.8	1.52	-	104	-	3.58
Mini-bag	2142	-	214	-	1927	-
Combined	132	1.5	3.5	102	31.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-13 Rev 09/09



Fresenius Medical Care

Fresenius Medical Care NA
 Waltham, MA 02451
 1-800-323-5188



(01) 003 49230 191 98 1

DELFLX[®] Neutral pH
PERITONEAL DIALYSIS SOLUTION
with 2.5% DEXTROSE
and attached **stay•safe[®]** Exchange Set

CAT. NO. 059-30312
NDC 49230-191-98

3000 mL
(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	2.5 g	-	2.54 g
Sodium Chloride, USP	567 mg	-	576 mg
Sodium Lactate	353 mg	2160 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	15.2 mg	-	15.4 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.6	1.52	-	104	-	3.56
Mini-bag	2142	-	214	-	1927	-
Combined	132	1.5	3.5	102	31.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only **DO NOT HEAT IN MICROWAVE OVEN**

89-926-14 Rev 09/09



Fresenius Medical Care

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188



(01) 003 49230 194 98 2

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 4.25% DEXTROSE

and attached **stay•safe®** Exchange Set

CAT. NO. 059-30314

3000 mL

NDC 49230-194-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	4.25 g	-	4.32 g
Sodium Chloride, USP	567 mg	-	576 mg
Sodium Lactate	353 mg	2160 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	15.2 mg	-	15.4 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	98.6	1.52	-	104	-	3.56
Mini-bag	2142	-	214	-	1927	-
Combined	132	1.5	3.5	102	31.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile, Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only DO NOT HEAT IN MICROWAVE OVEN

89-926-15 Rev 09/09



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(01) 003 49230 197 98 3

DELFLIX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 1.5% DEXTROSE

LOW MAGNESIUM

and attached **stay•safe®** Exchange Set

CAT. NO. 059-30301

3000 mL

NDC 49230-197-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	1.5 g	-	1.52 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	96.6	-	3.56
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	36.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only DO NOT HEAT IN MICROWAVE OVEN

89-926-10 Rev 09/09



Fresenius Medical Care

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(01) 003 49230 200 98 0

DELFLIX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 2.5% DEXTROSE

LOW MAGNESIUM

and attached **stay•safe®** Exchange Set

CAT. NO. 059-30302

3000 mL

NDC 49230-200-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrated, USP	2.5 g	-	2.54 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	96.6	-	3.56
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	36.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-11 Rev 09/09



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(01) 003 49230 203 98 1

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 4.25% DEXTROSE

LOW MAGNESIUM

and attached **stay•safe®** Exchange Set

CAT. NO. 059-30304

3000 mL

NDC 49230-203-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	4.25 g	-	4.32 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	25.7 mg	-	26.1 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	96.6	-	3.56
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	36.5	3.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

DO NOT HEAT IN MICROWAVE OVEN

Rx only

89-926-12 Rev 09/09



Fresenius Medical Care

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(01) 003 49230 206 98 2

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 1.5% DEXTROSE

LOW MAGNESIUM / LOW CALCIUM

and attached **stay•safe®** Exchange Set

CAT. NO. 059-30321

3000 mL

NDC 49230-206-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrous, USP	1.5 g	-	1.52 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	18.4 mg	-	18.7 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	98.6	-	2.54
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	38.5	2.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only DO NOT HEAT IN MICROWAVE OVEN

89-926-16 Rev 09/09



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Waltham, MA 02451
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(01) 003 49230 209 98 3

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 2.5% DEXTROSE

LOW MAGNESIUM / LOW CALCIUM

and attached **stay•safe®** Exchange Set

CAT. NO. 059-30322

3000 mL

NDC 49230-209-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrated, USP	2.5 g	-	2.54 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	18.4 mg	-	18.7 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	96.6	-	2.54
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	36.5	2.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

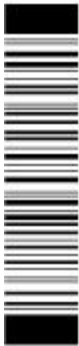
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89-926-17 Rev 09/09



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(01) 003 49230 212 98 3

DELFLEX® Neutral pH

PERITONEAL DIALYSIS SOLUTION

with 4.25% DEXTROSE

LOW MAGNESIUM / LOW CALCIUM

and attached **stay•safe®** Exchange Set

CAT. NO. 059-30324

3000 mL

NDC 49230-212-98

(Approx. 60 mL excess)

Values for ingredients listed below as "Combined" reflect the total content AFTER mixing with the mini-bag solution.

Each 100 mL contains:	Combined	Mini-bag	Main Bag
Dextrose Hydrated, USP	4.25 g	-	4.32 g
Sodium Chloride, USP	538 mg	-	547 mg
Sodium Lactate	409 mg	2500 mg	-
Sodium Bicarbonate	29.4 mg	1800 mg	-
Calcium Chloride, USP	18.4 mg	-	18.7 mg
Magnesium Chloride, USP	5.08 mg	-	5.16 mg
Water for Injection, USP	q.s.	q.s.	q.s.
pH	7.0 ± 0.4		

May contain Hydrochloric Acid or Sodium Hydroxide for pH adjustment.

APPROXIMATE MILLEQUIVALENTS PER LITER

	Sodium	Magnesium	Bicarbonate	Chloride	Lactate	Calcium
Main Bag	93.5	0.51	-	96.6	-	2.54
Mini-bag	2448	-	214	-	2233	-
Combined	132	0.5	3.5	95	36.5	2.5

Potassium Chloride to be added only under the direction of a physician.

Sterile. Non-pyrogenic. For Intraperitoneal Administration Only.

Store in outerwrap at 25°C (77°F) until ready for use. See Insert.

Inspect inner bags by squeezing firmly. Discard if leaks are found.

Use aseptic technique. Use only if solutions are clear and container is undamaged. Discard unused portion.

Usual Dosage: See Insert.

NO LATEX: This product and its packaging do not contain any latex materials.

Read package insert for full instructions

Rx only DO NOT HEAT IN MICROWAVE OVEN

89-926-18 Rev 09/09



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